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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,028	02/28/2005	Zhihui Liu	09548.1060USWO	4794

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,028	LIU ET AL.	
	Examiner	Art Unit	
	ANDREW D. KOSAR	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments/Arguments

Applicant's amendments and arguments filed December 30, 2008 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Claims 5 and 11 have been canceled. Claims 1-4 and 6-10 are pending and have been examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JEFFERIES (US Patent 5,948,426) and RODAN (US Patent 5,461,034).

Applicant argues that the teachings of Jefferies and Rodan lack any teaching or suggestion for the instantly claimed composition and are directed towards bone marrow reconstruction. Applicant further argues that the claims provide a synergistic effect on blood cell formation that is not suggested or recognized by the prior art.

With regards to Applicant's arguments that the prior art lacks any teaching or suggestion, it should be noted that *KSR* forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obviousness (*See Ex Parte Smith*, USPQ2d, slip op. 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR v. Teleflex*, 82 USPQ2d 1396). Furthermore, in response to applicant's argument that the prior art does not suggest or recognize the composition would provide a synergistic effect on blood cell formation, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Here, the art recognizes the two are useful for a different purpose, and as set forth in *Kerkhoven*, below, the combination of the two elements flows logically from the two being taught in the prior art for the same purpose. Additionally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., provide a synergistic effect on blood cell formation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the claims are to a composition and method of making the composition and not to a method of use, and thus arguments of synergism do not outweigh the obviousness of the combination as set forth in the prior art. Thus, the rejection is maintained.

Jefferies teaches that, "Examples of growth factors that are suitable for the expansion of hematopoietic tissue in the collagen-DFDBA conjugate composites of the present invention

include, but are not limited to, interleukin-4, interleukin-6, interleukin-7, platelet-derived growth factor, alpha interferon species, tumor necrosis factor (TNF), TGF-beta and TNF-alpha proteins, colony-stimulating factors, such as granulocyte colony-stimulating factor, stem cell proliferation factor, osteogenic growth polypeptide, autocrine growth factor, and the like, and their combinations." (column 6, lines 17-26).

Jefferies further provides various compositions and means of delivery as well as making the pharmaceutical compositions (e.g gel, powder, lyophilized sponge, combinations thereof, lyophilized sponge reground and reconstituted in pharmaceutical carrier- column 5, lines 12-65).

Rodan teaches the peptide ALKRQGRTKYGFGG (abstract) which is instant SEQ ID NO:1. Rodan teaches that this peptide is, "likely to enhance the hemopoietic microenvironment and consequently stimulate hemopoiesis at the noncommitted stem cell level avoiding the stem cell depiction and white cell discrimination." (column 3, lines 33-38) and teaches pharmaceutical compositions and methods of use to stimulate hematopoietic reconstruction (e.g. claims 16-19).

Rodan additionally teaches that, "The currently available clinical (experimental) treatment for stimulating post BMT marrow reconstruction consists mainly of the administration of recombinant human granulocyte colony stimulating factor (rhG-CSF) and/or recombinant human granulocyte-macrophage colony stimulating factor (rhGM-CSF) [Blazar R. B., et al. (1989) Blood 74:2264]. These cytokines affect directly the proliferation of transplanted pluripotent cells already committed to the white-cell lineages [Vellenga E., et al. (1987) Leukemia 1:584] and consequently decrease the time to leukocyte and neutrophil recovery." (column 2, line 40-50).

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

Here, the OGP, G-CSF and GM-CSF are all known for the very same purpose of bone marrow reconstruction, thus it would have been obvious to have combined the components into a composition for the very same purpose with the expectation that it would function to facilitate bone marrow reconstruction.

With regards to the form, e.g. lyophilized or in solution, both references teach various pharmaceutical compositions, and selection of a desired form is well within the purview of the artisan to determine which form is desired, each being equally identified as capable of being used for practicing the methods of Jefferies and Rodan.

Further, although Jefferies and Rodan do not teach a method of using a composition comprising the specifically claimed concentration of the compounds for OGP and G-CSF, absent evidence to the contrary, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have optimized the concentration for both components. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the

forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654